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APPLICATION NO. FIRST NAMED INVENTOR FILING DATE ATTORNEY DOCKET NO. CONFIRMATION NO. 09/872,815 06/01/2001 Donald P. Reitberg 653.1006 3381 23280 7590 09/11/2003 DAVIDSON, DAVIDSON & KAPPEL, LLC **EXAMINER** 485 SEVENTH AVENUE, 14TH FLOOR LY, CHEYNE D NEW YORK, NY 10018 ART UNIT PAPER NUMBER 1631

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| - | | Application No. | Applicant(s) | Applicant(s) | |
|--|---|--|---|---------------------|--|
| Office Action Summary | | 09/872,815 | REITBERG, DONALD | REITBERG, DONALD P. | |
| | | Examiner | Art Unit | | |
| | | Cheyne D Ly | 1631 | | |
| Period fo | The MAILING DATE of this communication ap or Reply | pears on the cover sheet | vith the correspondence addres | SS | |
| THE I - Exte after - If the - If NO - Failu - Any i | ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. Insions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. In period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period are to reply within the set or extended period for reply will, by statutively received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b). | 136(a). In no event, however, may a ply within the statutory minimum of the will apply and will expire SIX (6) MC e, cause the application to become a | a reply be timely filed irty (30) days will be considered timely. ONTHS from the mailing date of this common (ABANDONED) (35 U.S.C. § 133). | unication. | |
| | Posponaive to communication(s) filed on | | | | |
| 1)[_] | Responsive to communication(s) filed on | · | | | |
| 2a)∐ | | his action is non-final. | allara mussassitian as to the m | anita in | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims | | | | | |
| 4) Claim(s) 1-35 is/are pending in the application. | | | | | |
| , | 4a) Of the above claim(s) is/are withdra | | | | |
| | Claim(s) is/are allowed. | | | | |
| · <u> </u> | S) Claim(s) is/are rejected. | | | | |
| | Claim(s) is/are objected to. | | | | |
| | Claim(s) <u>1-35</u> are subject to restriction and/or | election requirement. | | | |
| | on Papers | • | | | |
| 9) The specification is objected to by the Examiner. | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| 11) 🗌 | The proposed drawing correction filed on | _ is: a)☐ approved b)☐ | disapproved by the Examiner. | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | |
| Priority ι | ınder 35 U.S.C. §§ 119 and 120 | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | |
| a) | All b) Some * c) None of: | | | | |
| | 1. Certified copies of the priority documen | ts have been received. | | | |
| | 2. Certified copies of the priority document | ts have been received in | Application No | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | |
| a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | |
| Attachmen | | [21 3.12] 2.1.2.2.2 | 00 | | |
| 1) Notic 2) Notic | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) _ | 5) Notice o | v Summary (PTO-413) Paper No(s) f Informal Patent Application (PTO-15 | | |

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

2. This application contains claims directed to the following patentably distinct species of he claimed invention:

Species (A):

- 3. Species of wherein the method requires an unspecified number of drugs or requires a first and second drug, which are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to select the method wherein said method requires an unspecified number of drugs or requires a first and second drug.
- 4. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 12-22 are generic to the above species.

 Species (B):
- 5. Species of testing methodologies are cited in claim 4, which are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to select a type of testing methodologies from those listed in claim 4.
- 6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-35 are generic to the above species in all Groups.

 Species (C):

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7. Species of drugs are cited in claim 10, which are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to select an unspecified type of drug or a type of drug from those listed in claim 10.

- 8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-35 are generic to the above species.
- 9. Applicant is advised that a reply to this requirement must include an identification of a specie from each specie set (A-C) cited above that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
- 10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
- 11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

- 13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 14. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 193), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.
- 15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.
- 16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.
- 17. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly 9/4/03

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